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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ANDERSON, JAMES D	
ART UNIT	**PAPER NUMBER**
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/777,043	RAPAPORT, ELIEZER	
	Examiner	Art Unit	
	James D. Anderson	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 4-13* is/are rejected.

7)☒ Claim(s) *13* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

CLAIMS 1-2 & 4-13 ARE PRESENTED FOR EXAMINATION

Applicants' amendment filed 7/19/2007 has been received and entered into the application. Accordingly, claims 1-2 and 10-11 have been amended and claim 13 has been added.

Applicants' arguments, filed 7/19/2007, have been fully considered and are deemed to persuasive with respect to the 35 U.S.C. § 112, 1st Paragraph (Enablement) rejection set forth in the previous Office Action. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Interpretation

Upon further consideration of the scope of the claimed subject matter, it is apparent to the Examiner that the claims 1-2 and 7-13 encompass "administration" of any amount of AMP or ATP. This includes a single molecule of such compounds. As such, any normal diet wherein cellular matter is consumed reasonably reads on the claims because all cells have AMP and ATP in them. Accordingly, in view of the above broadest reasonable interpretation of the claims, new art rejections are herein being applied to the instant claims.

Claim Objections

Claim 13 is objected to under 37 CFR § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is

required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In the instant case, claim 13 depends from claim 1 or claim 2. Claims 1 and 2 recite administration to a human a member selected from caffeine or theophylline and a member selected from adenosine and inorganic phosphate, AMP, or ATP. However, claim 13 recites administration of a composition comprising a magnesium 2+ compound and AMP and/or ATP, as well as "pharmaceutically acceptable salts *thereof*, chelates *thereof*, metal complexes *thereof* or liposomes *thereof*". As such, claim 13 expands, rather than limits, claim 1 or claim 2.

Claim Rejections - 35 USC § 112 (2nd Paragraph)

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-6 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 2 were amended to recite administration of "adenosine and inorganic phosphate". Claims 4-6 recite dose ranges of ATP, AMP, or adenosine. However, since claims 1 and 2 require that adenosine be administered in combination with inorganic phosphate, it is not clear whether the doses recited in claim 4-6 apply to only adenosine, or whether they are intended to apply to the total of adenosine and inorganic phosphate.

Claim 13 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear to what the claimed "pharmaceutically acceptable

salts *thereof*, chelates *thereof*, metal complexes *thereof* or liposomes *thereof*" refer. Are these referring to the magnesium 2+ compound or to AMP or ATP?

Claim Rejections - 35 USC § 112 (1st Paragraph)

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 13 is rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a Written Description and New Matter rejection.

Regarding the requirement for adequate written description of chemical entities, Applicant's attention is directed to the MPEP §2163. In particular, *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089, 118 S. Ct. 1548 (1998), holds that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish or plain for obtaining the claimed chemical invention." *Eli Lilly*, 119 F.3d at 1566. The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office ("PTO") Guidelines for Examination of Patent Applications under the 35 U.S.C. 112.I "Written Description" Requirement ("Guidelines"), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met

by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics," including, *inter alia*, "functional characteristics when coupled with a known or disclosed correlation between function and structure..." *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 316, 1324-25 (Fed. Cir. 2002) (quoting *Guidelines*, 66 Fed. Reg. at 1106 (emphasis added)). Moreover, although *Eli Lilly* and *Enzo* were decided within the factual context of DNA sequences, this does not preclude extending the reasoning of those cases to chemical structures in general. *Univ. of Rochester v. G.D. Searle & Co.*, 249 Supp. 2d 216, 225 (W.D.N.Y. 2003).

Applicant has failed to provide any structural characteristics, chemical formula, name(s) or physical properties, aside from the express identification of magnesium stearate, that would provide adequate written description of the genus of compounds encompassed by "magnesium 2+ compound". Further, the recited genus of "magnesium 2+ compound" is new matter that is not supported by the originally filed disclosure. The specification only provides support for magnesium stearate, not for the genus "magnesium 2+ compound".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 7, 9-10 and 12-13 are rejected under 35 U.S.C. § 102(b) as being anticipated by Friedlander (U.S. Patent No. 5,055,460; Issued Oct. 8, 1991) as evidenced by Lehninger (Biochemistry, Worth Publishers, Inc., New York, 1970, pages 289-290).

The instant claims recite administration of caffeine and adenosine and inorganic phosphate, AMP, or ATP in order to induce weight loss of maintain weight reduction in human patients.

Friedlander teaches compositions comprising caffeine, aspirin, and ephedrine, which may be administered concurrently with caloric restriction or with a commercial diet program, for the purpose of reducing weight or maintaining body weight (Abstract; col. 4, lines 15-22). The amount of caffeine is taught to be in the range of 10-500 mg/day, thus reasonably anticipating the instantly claimed 0.1-100 mg/kg/day and 0.1-10 mg/kg/day (col. 4, lines 29-31). The compositions are administered orally or parenterally, thus anticipating the claimed "oral" and "injection" administration routes (col. 5, lines 22-26).

With respect to the claimed "administration" of adenosine and inorganic phosphate, AMP, or ATP, Lehninger is provided as supporting evidence that the consumption of a normal diet will naturally result in the "administration" of ATP and/or AMP as instantly claimed. For example, Lehninger teaches that ATP, ADP, and AMP "...are not trace substances; the sum of their concentrations in the aqueous phase of various types of intact cells is between 2 and 15 mM" (page 289). These nucleotides are present not only in the soluble cytoplasm but also within organelles such as mitochondria and nuclei (id.). With respect to claim 13, Lehninger teaches that very little ATP exists as a free anion, rather, it is largely present as a 1:1 $MgATP^{2-}$ complex (page 290).

Accordingly, it is the Examiner's position that the consumption of a normal diet or a commercial diet plan will naturally result in the consumption of at least one molecule of AMP or ATP because these substances are present in all cells, including the cells of beef products, fish products, chicken products, vegetables, etc.

Claims 1-2 and 7-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Astrup (U.S. Patent No. 5,422,352; Issued Jun. 6, 1995) as evidenced by Lehninger (Biochemistry, Worth Publishers, Inc., New York, 1970, pages 289-290).

The instant claims recite administration of caffeine and adenosine and inorganic phosphate, AMP, or ATP in order to induce weight loss of maintain weight reduction in human patients.

Astrup teaches compositions comprising caffeine and ephedrine for the purpose of reducing weight of a human (Abstract). Theophylline is also taught to be a reasonable substitute for caffeine, as both are thermogenically active xanthines (col. 6, line 65 to col. 7, line 6). The amount of caffeine or other xanthine is taught to be in the range of 80 mg to 1.9 grams per unit dose, preferably 80 mg to 720 mg, and can be administered 1 to 10 times daily, thus reasonably anticipating the instantly claimed 0.1-100 mg/kg/day and 0.1-10 mg/kg/day (col. 8, lines 52-59). The compositions are administered "by any suitable route" such as orally, topically, or parenterally, thus anticipating the claimed "oral", "injection", and topical administration routes (col. 8, lines 60-66). In one study, participants were administered caffeine tablets, ephedrine tablets, or caffeine/ephedrine tablets and were allowed to eat freely after a light breakfast and standardized lunch (col. 23, lines 29-52).

With respect to the claimed "administration" of adenosine and inorganic phosphate, AMP, or ATP, Lehninger is provided as supporting evidence that the consumption of a normal diet will naturally result in the "administration" of ATP and/or AMP as instantly claimed. For example, Lehninger teaches that ATP, ADP, and AMP "...are not trace substances; the sum of their concentrations in the aqueous phase of various types of intact cells is between 2 and 15 mM" (page 289). These nucleotides are present not only in the soluble cytoplasm but also within organelles such as mitochondria and nuclei (id.). With respect to claim 13, Lehninger teaches that very little ATP exists as a free anion, rather, it is largely present as a 1:1 $MgATP^{2-}$ complex (page 290). Accordingly, it is the Examiner's position that the consumption of a normal diet or a commercial diet plan will naturally result in the consumption of at least one molecule of AMP or ATP because these substances are present in all cells, including the cells of beef products, fish products, chicken products, vegetables, etc.

Claims 1-2, 7, 10, 12 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Allen (U.S. Patent No. 5,480,657; Issued Jan. 2, 1996) as evidenced by Lehninger (Biochemistry, Worth Publishers, Inc., New York, 1970, pages 289-290).

The instant claims recite administration of caffeine and adenosine and inorganic phosphate, AMP, or ATP in order to induce weight loss of maintain weight reduction in human patients.

Friedlander teaches compositions comprising caffeine, fructose, and chromium for the purpose of reducing weight or maintaining body weight, which may be consumed with meals (Abstract; col. 10, lines 15-33). The amount of caffeine is taught to be in the

range of 30-150 mg, thus reasonably anticipating the instantly claimed 0.1-100 mg/kg/day and 0.1-10 mg/kg/day (col. 3, lines 59-67). The compositions are administered orally (*i.e.*, as a beverage), thus anticipating the claimed "oral" administration route (col. 4, lines 8-14).

With respect to the claimed "administration" of adenosine and inorganic phosphate, AMP, or ATP, Lehninger is provided as supporting evidence that the consumption of a normal diet will naturally result in the "administration" of ATP and/or AMP as instantly claimed. For example, Lehninger teaches that ATP, ADP, and AMP "...are not trace substances; the sum of their concentrations in the aqueous phase of various types of intact cells is between 2 and 15 mM" (page 289). These nucleotides are present not only in the soluble cytoplasm but also within organelles such as mitochondria and nuclei (id.). With respect to claim 13, Lehninger teaches that very little ATP exists as a free anion, rather, it is largely present as a 1:1 $MgATP^{2-}$ complex (page 290). Accordingly, it is the Examiner's position that the consumption of a normal diet or a commercial diet plan will naturally result in the consumption of at least one molecule of AMP or ATP because these substances are present in all cells, including the cells of beef products, fish products, chicken products, vegetables, etc.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

James D. Anderson
Patent Examiner
AU 1614

October 17, 2007

Ardin H. Marschel 10/21/07
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SUPERVISORY PATENT EXAMINER